



Department of Public Health and Human Services

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Steve Bullock, Governor

Richard H. Opper, Director

TO: Montana Ambulance Services

FROM: Montana Department of Public Health and Human Services
Certification Bureau

DATE: August 12, 2015

RE: CLIA Certificate Requirement

Deadline: September 30, 2015

The Clinical Laboratory Improvement Amendments (CLIA), passed by Congress in 1988, require all facilities that test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings to have a CLIA certificate in order to operate (42 Code of Federal Regulations (C.F.R.), Part 493).

Currently, a CLIA certificate is not on file for your ambulance service. If your service performs any laboratory tests, such as glucose finger sticks, the service must have a CLIA certificate on file. The type of certificate is determined by the complexity of the testing you perform (waived, moderate, or high complexity) as classified by the Food and Drug Administration (FDA).

To be compliant with federal law, you need to apply for a CLIA Certificate on a CMS-116 form or provide this office with a copy of the CLIA certificate under which you operate **by September 30, 2015**. Details for the certificate types are outlined below:

Certificate Types

A Certificate of Waiver is required when all the tests performed by the ambulance service are categorized as 'waived' complexity by the FDA. A **glucometer** is an example of a waived test. A waived categorization does not mean that you do not need a certificate in order to perform the test. The waived regulations require you to maintain a current certificate and follow all manufacturers' instructions found in reagent package inserts, instrument operator's manuals and technical bulletins, in order to remain compliant.

Any person may conduct a waived test, and any person may be the laboratory director for a Certificate of Waiver. The laboratory director is responsible for ensuring that all of the manufacturer's instructions are followed for each test, all personnel are trained properly, and proper documentation is maintained.

Five percent of Certificates of Waiver are chosen randomly each year to receive an educational visit with the Montana State CLIA surveyor. These are completed at no cost to the facility and are focused on increasing quality laboratory practice.

A Certificate of Compliance is required when at least one of the tests performed by the ambulance service is categorized as moderate or high complexity by the FDA. **Blood gases** are an example of moderate/high complexity analytes.

All testing personnel, including the laboratory director, performing moderate/high complexity tests must qualify with licensing, education, and experience to perform those tests. The laboratory director is responsible for ensuring compliance with all CLIA federal regulations (all subsections of 42 C.F.R. § 493 apply).

All Certificates of Compliance are subject to biennial surveys to ensure compliance with the federal regulations. The certificate holder is responsible for the cost of this survey.

CLIA Application Information

The CLIA application (form CMS-116) can be downloaded from www.cms.gov/CLIA under the "How to Apply for a CLIA Certificate" tab or at <http://dphhs.mt.gov/qad/Certification/CLIA>. Completed applications may be faxed to 406-444-3456, emailed to mtssad@mt.gov, or mailed to the Certification Bureau-2nd floor at P.O. Box 202953 in Helena, MT 59620. You will be assigned a CLIA number at the time of application entry. Applications must be complete and signed by the appointed laboratory director. Please enclose the laboratory director's credentials when applying for a Certificate of Compliance.

Billing Information

A bill will be sent to your address within a few weeks of your application submission. Do not send payment to the state office with your application. A Certificate of Waiver is \$150.00 for a two year certificate. The cost of a Certificate of Compliance depends on the volume of testing performed per year, starting at \$450.00 for a two year certificate for the lowest volume (<2000 tests/year) category. You may pay the bill by mail or online using www.pay.gov. This will require your new CLIA number.

Please be aware that purposely failing to comply with this requirement may result in termination of the Medicare/Medicaid provider agreement for the ambulance service. CMS makes that decision based on the information provided by this office.

Further information can be found at www.cms.gov/CLIA. If you have additional questions regarding CLIA certification, please feel free to contact Joyce Shepard at the Certification Bureau at 406-444-2099.

Sincerely,

Jill Caldwell, RN, MSN

Certification Bureau